## REMARKS

Claims 1-15 were originally presented. New claims 16-19 were presented in the response filed December 17, 2007. Claims 1-8, and 18 are revised herein. New claims 20-21 are submitted herein. The claims presently under consideration are thus claims 1-21, as set forth herein. These claims are supported by the specification as filed, and Applicant believes that no new matter has been added. Applicant respectfully requests that the Examiner reconsider and withdraw the various grounds of rejection of the claims.

***Detailed Action***

On page two of the Office Action, the Examiner has acknowledged receipt of Applicant's Amendment/Remarks, IDS and Terminal Disclaimer filed December 17, 2007. The Examiner states that the filed terminal disclaimer has been reviewed and is accepted and thus the provisional Double Patenting rejection has been withdrawn.

On pages 2-3 of the Office Action, the Examiner maintains rejections of claims 1 and 4-19 under 35 U.S.C. 112 first paragraph. The Examiner states while being enabling for "optically transparent" the specification does not reasonably provide enablement for a contact lens having nanoparticles dispersed therein. The Examiner suggests that Applicant incorporate the limitations of claim 2 into claim 1.

Applicant respectfully traverses this rejection. Under 35 U.S.C. 112 first paragraph the patentee must disclose in the patent sufficient information to put the public in possession of the invention and to enable those skilled in the art to make and use the invention. Applicant submits that the application as filed provides an appropriate level of instruction as to the disclosed drug delivery system. For example, the specification states:

- "The particle size of the nanoparticles and the number thereof dispersed in the contact lens are such that the contact lens remains substantially transparent." See for example, page 3.
- "the nanoencapsulated ophthalmic drug is substantially uniformly dispersed throughout the contact lens." See for example, Page 6.
- "If the nanoparticle size and loading are sufficiently low, the particle-loaded lens is transparent. The limiting size of the drug-laden nanoparticles is ultimately dependent on the refractive index thereof, but generally is less than about 50 nm to 200 nm." See for example, Page 7.
- "In the case of particle laden lenses, since particles control the long time release rates, the time of release is relatively independent of the lens thickness." See for example, Page 20.
- "The drug concentration in water varies almost as $t^{1/2}$ implying that the diffusion resistance in the hydrogel is controlling the drug release at short times. However at longer times the drug release rates are controlled by the particles. Release rates are very high during the first day, and after the first day they became considerably slower than the short-term release rates. After a 10 day period, concentration of drug in water levels off, implying an equilibrium between the drug concentration in oil drops, the concentration in the hydrophilic hydrogel matrix and the concentration in water. This behavior of the data implies the presence of two different time scales that can be fitted into two exponential curves with an equation of the form:

$$C_1 (1 - e^{-t/\Gamma_1}) + C_2 (1 - e^{-t/\Gamma_2})$$ where $C_1$ and $C_2$, $\Gamma_1$ and $\Gamma_2$ are empirical constants." See for example, Page 21.

- "The drug delivery rates can be controlled by tailoring the microstructure of the hydrogel and manipulating the size, concentration and structure of the nanoparticles and the concentration of the drug in the particles." See for example, Page 27.

Factors to be considered when evaluating whether there is undue experimentation include: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the relative skill of those in the art, 7) the predictability or non predictability of the art, and 8) the breadth of the claims. In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Thus, with respect to enablement the relevant inquiry lies in the relationship between the specification, the claims, and the knowledge of one of ordinary skill in the art. If, by following the steps set forth in the specification, one of ordinary skill in the art is not able to replicate the claimed invention without undue experimentation, the claim has not been enabled as required. Applicant submits that one of ordinary skill in the art is enabled upon review of the present specification to practice the invention as claimed, without undue experimentation.

The present application discloses a means of controlling the relate rate of an ophthalmic dug such that the time of release is extended as compared to ophthalmic drugs directly trapped in the contact lens during polymerization. As disclosed, this release rate is controlled by items such as: microstructure of the encapsulation material; size, concentration or structure of the nanoparticles; and concentration of the ophthalmic drug. As set forth in claim 1, the practitioner would select an encapsulation material, such that a hydrophobic encapsulation material is selected for a hydrophobic ophthalmic drug and a hydrophilic encapsulation material is selected for a hydrophilic ophthalmic drug. In

addition, the practitioner would select nanoparticle size and concentration dependent upon his/her desire as to drug delivery rate and transparency, see for example dependent claims 2, and 3.

Applicants request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 112 first paragraph.

On pages 3-4 of the Office Action, the Examiner has rejected claims 1, 2, 4, 5, 9, 12, and 13 under 35 U.S.C. 102(e) as being anticipated by Resnick [US 2002/0141760 A1] (hereinfafter Resnick). Applicant notes that the Resnick application was abandoned May 17, 2004. There should thus be no presumption that this application has an enabling disclosure for all disclosed subject matter. Applicant continues to submit that the focus and intent of Resnick's invention is very different from that of the current invention, and that Resnick does not enable a person of ordinary skill to load nano/microspheres into contact lenses for the purpose of extended drug delivery.

Applicant notes that it has long been a tenant of patent law that a disclosure cannot anticipate a claimed invention if it is not enabling; *see for example, Seymore v. Osborne*, 78 U.S. 516 (1870); *Paperless Accounting Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). The reference must describe the invention in such a way as to put one of ordinary skill in the art of the field of the invention in possession. Thus, one of ordinary skill must not only be able to comprehend the invention, but must also be able to produce and use the invention. Mere speculation or a general representation does not constitute anticipation. As written by Judge Learned Hand:

> No doctrine of the patent law is better established than that a prior patent or other publication must bear within its four corners adequate directions for the practice of the patent invalidated. If the earlier disclosure offers no

> more than a starting point for further experiments, if its teaching will sometimes succeed and sometimes fail, if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge and is not an anticipation. *Dewey & Almy Chem. Co. v. Mimex Co.*, 124 F.2d 986 2d Cir. (1942).

The Examiner points to paragraph 3 as teaching contact lens containing nanospheres incorporated directly therein. In paragraph 6, Resnick states:

> The instant invention is enabled through alteration and improvement of conventional contact lenses by incorporated of the microspheres or nanospheres into the actual lens during manufacture through fabrication of a new shaped matrix incorporating microspheres (including nanospheres) containing reflective or adsorptive substances, or by application of a coating comprising substrate, carrier microspheres, binder and chemicals, in a matrix or comprising layers of coating comprising a matrix, or comprising a series of matrixes, to be applied as a coating to existing lenses or new manufactures, or alternatively to both.

However, this paragraph 3 does not provide enablement as to: size, concentration or structure of the nanoparticles; effectuating time release of a nanoencapsulated ophthalmic drug; or controlling release rate of the nanoencapsulated ophthalmic drug.

The Examiner further cites to paragraph 6 within Resnick as providing disclosure for a contact lens containing nanoparticles incorporated directly therein: "[...] or by incorporating an energy-absorbent substance directly into the lens (via microspheres or nanospheres) during the manufacture process [...]." Again, Applicant submits that this disclosure does not enable one to practice the present invention as claimed.

The Examiner points to paragraph 19 as teaching methods of incorporating drugs and therapeutic agents into the contact lens for the purpose of drug delivery to the eye. Applicant notes that Resnick refers to drug delivery from these lenses in a very general fashion in paragraph 19. Here Resnick states:

> A further aspect of the invention is a novel chemical or gas delivery system which may be used in combination with the instant system to accomplish levage of the organ (eye) or to treat injuries by application of time-released substances directly onto the surface of

> the cornea or to the overall surface of the organ (eye), after or prior to injury, or during incidences of battle, for example, or while recovering from eye or facial surgery or injuries. I shall cause the filing of a separate patent application, without traverse, concerning this aspect of the invention, but mention it here, only to document discovery and concept dates as a matter of record.

Applicant submits that the above paragraph is not an enabling disclosure.

- Resnick does not enable a person having ordinary skill in the art to provide extended or time release delivery of ophthalmic drugs by nanencapsulating such drugs and dispersing within a contact lens.
- Resnick does not teach on selecting encapsulation material dependent upon ophthalmic drug characteristics.
- Resnick does not teach the selection of a hydrophobic encapsulation material generally or a microemulsion specifically for a hydrophobic ophthalmic drug.
- Resnick does not teach the selection of a hydrophilic encapsulation material generally or a liposome specifically for a hydrophilic ophthalmic drug
- Resnick does not teach on the issue of duration of release. Specifically, while Resnick refers generally to time-released substances there is no disclosure directed to controlling this release rate.
- Resnick does not teach that the particles have to be designed specifically for a given drug such that they attenuate the drug release rates from the lens.
- Resnick does not teach substantially uniformly dispersing the nanoencapsulated ophthalmic drug is throughout the contact lens.
- Resnick does not teach that sufficiently low nanoparticle size and loading results in a transparent lens.
- Resnick does not teach a preferred drug-laden nanoparticle size.

- Resnick does not teach that in the case of particle laden lenses, particles control the long time release rates, and that the time of release is relatively independent of the lens thickness.
- Resnick teaches neither release rate time scales nor mathematical formulas defining same.
- Resnick does not teach means of controlling the drug delivery rates such as tailoring the microstructure of the hydrogel and manipulating the size, concentration and structure of the nanoparticles and the concentration of the drug in the particles.
- Resnick does not disclose an amount of nanoparticles from about 1 to about 5%, by weight, based on the weight of the contact lens, as defined by claim 3.
- Resnick does not provide instruction as to the main issues relevant to transparency including particle size, loading and refractive index contrast.
- The Examples provided by Resnick in Figures 1-3 illustrate systems that would not be transparent because of the high degree of loading evident in the figures; thus teaching away form the present invention.

Anticipation requires that each and every element of the claimed invention be disclosed in a single reference. Further, to anticipate, the identical subject matter must not only be previously known, but the knowledge must be sufficiently enabling to place the information in the possession of the public. Thus mere naming or providing a description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the

date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). Applicant submits that Resnick does not provide an enabling disclosure. Please see also Applicant's affidavit as to the non-enabling nature of Resnick.

On pages 4-6, the Examiner has rejected claims 10, 11, 14 and 15 under 35 U.S.C. 103 as being unpatentable over Resnick. Applicant traverses. Unlike the present invention, which is directed to a drug delivery system, Resnick is directed to a means of protecting the eye. For the reasons set forth more fully above, Resnick would not enable one of ordinary skill in the art to practice the present invention.

***Response to Arguments***

On pages 6-11 the Examiner responds to Applicant's previously made arguments. First the Examiner expresses appreciation for the amendment to claim 2 providing the definition as to "optically transparent". However, the Examiner requests that this limitation be incorporated into claim 1. Given that claim 1 does not include the element "optically transparent"; Applicant does not understand why this term needs to be further defined within this claim. As further set forth herein, Applicant submits that the present specification enables one of ordinary skill in the art to practice the present invention and does provide an enabling description for a contact lens having nanoparticles dispersed therein.

The Examiner further states that Applicant's amendment renders the rejections of claims under 35 USC 112, second paragraph moot. The Examiner withdraws all previously noted rejections under this status. However, the Examiner does state that new

rejections have emerged. These will be more fully discussed in the New Rejections section below.

The Examiner states that Applicant's amendment of claim 12 renders the rejection under 35 USC 101/112 moot and that said rejection has been withdrawn.

On pages 7-11 the Examiner responds to Applicants arguments related to Resnick. The Examiner states that "Resnick clearly teaches 'drug delivery' and 'time release' at paragraph 19 and claims 2 and 12". Applicant traverses. Again, the Resnick specification makes only a non-enabling "passing reference" to the concept of time release drug delivery. Such a passing reference does not constitute an enabling disclosure.

Applicant submits that in order to be enabling the specification must contain certain information that would be necessary to one of ordinary skill in the art for that person to practice the invention as claimed. The Examiner states on page two that "although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims". However, Applicant respectfully notes that the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003). Thus items cited as teachings that provide enablement, for example for controlling the release rate of a nanoencapsulated ophthalmic drug, do not each need to also be included as an element within a claim. There are two considerations in determining enablement. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation. One does not look to the claims but to the specification to

find out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-17 (Fed. Cir. 1983).

***New Rejections***

On page 11, the Examiner rejects claims 1-19 under 35 USC 112, second paragraph as being indefinite for failing to particularly point our and distinctly claim the subject matter that Applicant regards as the invention. Claims 1- 8, and 18 have been amended thereby rendering these rejections moot.

On pages 13-17 claims 6 and 17-19 are rejected under 35 USC 103(a) as being unpatentable over Resnick in view of Darougar. Applicant traverses this rejection. Darougar's patent teaches ophthalmic drug delivery through a device that is cylindrical in shape with a length of at least 8 mm and a maximum diameter not exceeding 1.9 mm. This device is designed to be inserted into the upper or the lower fornix. The teachings of this patent are substantially different from the present claims in view of the significant differences in the shape and the site of insertion. Contact lenses cover the cornea and thus are preferably transparent. Also, the contact lenses have to be kept hydrated in the packaging solution so that these do not change shape after insertion in the eye. Further, the contact lenses are only about 100 micron thick. The geometry of the device plays a very important role in drug delivery rates to the cornea. Applicant therefore submits that neither Resnick nor Darougar, either alone or in combination, disclose or suggest the combination of elements set forth claims 6 and 17-19. In light of this and in light of the remarks set forth above, Applicants request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 103.

Claims 6 and 16 are also rejected under 35 USC 103(a) as being unpatentable over Resnick in view of Raut. Raut teaches topical delivery of pyrimethamine for

ophthalmic applications. For a nanoparticle-laden contact lenses taught by Resnick to serve as efficient delivery vehicles for delivering this drug, it is essential that the nanoparticles have a very high partition coefficient for this drug, or else a majority of the drug in the lens with be outside the particles, leading to a very high burst release. Thus, without undue experimentation, it is not feasible for someone skilled in the art to claim that incorporation of pyrimethamine in lenses described by Resnick will lead to any improvement in the release profiles. In fact Resnick is silent on the need for the particles to be designed in a manner to have a high partitioning of the drugs, which is an important issue taught by the present patent application. Accordingly, Applicant therefore submits that neither Resnick nor Raut, either alone or in combination, disclose or suggest the combination of elements set forth claims 6 and 16. In light of this and in light of the remarks set forth above, Applicants request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 103.

Applicant has earnestly endeavored to place the application in condition for allowance and favorable action toward that end is respectfully requested. The Commissioner is hereby authorized to charge to Deposit Account No. 50-1165 (T2315-908542US02) any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper and to credit any overpayment to that Account. If any extension of time is required

in connection with the filing of this paper and has not been separately requested, such extension is hereby requested.

Respectfully submitted,

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